EXHIBIT 70

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Products Liability Litigation:	MDL No.: 15-2666 (JNE/FLN)
This Document Relates To: All Actions.	

VIDEOTAPED DEPOSITION OF WILLIAM R. JARVIS, M.D.
San Francisco, California
Tuesday, July 25, 2017

BY: HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR
CSR LICENSE NO. 12885
JOB NO. 124789

July 25, 2017
9:00 a.m.

Videotaped deposition of WILLIAM R. JARVIS, M.D., held at One Market Plaza, Spear Tower, San Francisco, California, before Heidi Belton, a Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, California Certified Realtime Reporter, Certified LiveNote Reporter, and NCRA Realtime Systems Administrator.

APPEARANCES:

For the Plaintiff:

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APPEARANCES (Continued):

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Also Present: Mordecai Boone, in-house counsel for 3M; Sean McGrath, videographer.

SAN FRANCISCO, CALIFORNIA
TUESDAY, JULY 25, 2017
9:00 a.m.

THE VIDEOGRAPHER: Good morning. This is the start of file number 1, Volume I of the videotaped deposition of Dr. William Jarvis, in the matter In re: Bair Hugger Forced Air Warming Products Liability Litigation in the United States District Court, District of Minnesota. MDL number 15-2666 (JNE/FLN).

This deposition is being held at 1 Market Plaza, Spear Tower, San Francisco, California on July 25, 2017, approximately 9:00 a.m. My name is Sean McGrath, from TSG Reporting, Incorporated and I'm a legal video specialist. The court reporter is Heidi Belton in association with TSG Reporting.

Would counsel please introduce yourselves, starting with the questioning attorney.

MR. C. GORDON: Corey Gordon, Blackwell Burke, on behalf of defendants.

MR. B. GORDON: Ben Gordon, on behalf of plaintiffs.

MR. COFFIN: Chris Coffin, Pendley, Baudin & Coffin, on behalf of plaintiffs.

MR. ASSAAD: Gabrielle Assaad, on behalf

But I think my primary concern was that they only looked at two specific rather than a broader range of particles. But they still found, you know, 35 colony-forming units per meter squared as a bacterial load in the operating room which is consistent with, again, finding airborne particles in the operating room. They just didn't find a correlation, but they were looking at too specific particle counts, not a wide range.

BY MR. C. GORDON:

Q. So on that basis you think that this would -- systematic review using the CDC gold standard methodology, this would not be something that would properly be considered in, say, coming up with a CDC guideline; is that right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, to be perfectly honest with you, in terms of the CDC guideline it wouldn't. Because right now the CDC guideline doesn't look at anything that's not a randomized control trial. I don't agree with it but that's what they do. So by definition CDC would not look at this at all.

(Reporter interruption.)

So from CDC's point of view, in terms of their -- for instance a surgical site guideline that

they have just recently updated, in that document they did not look at any study that was not a randomized control trial.

MR. C. GORDON: That's maybe an important distinction that we should talk about. Let me start off by marking Exhibit 5.

(Exhibit 5 marked.)

BY MR. C. GORDON:

Q. Could you tell me what that is, please.

A. This is a Centers for Disease Control and Prevention guideline for the prevention of surgical site infections 1999.

Q. And you were part of the CDC at that time; right?

A. That is correct.

Q. And you were part of a group of people who actually pulled together and prepared these guidelines; correct --

A. I --

Q. -- for this guideline?

A. I supervised this guideline.

Q. And so when you talk about the CDC methodological gold standard that you applied in coming up with your expert opinion in this case, would that be the same methodology that was employed

in coming up with the 1999 Exhibit 5?

A. To a large extent, yes.

Q. Are there any methodological differences?

A. Well, obviously here there's a -- what's called the Hospital Infection Control Practices Advisory Committee which is a federal advisory committee. So CDC -- a number of different groups at CDC have advisory committees. This was one for the hospital infections program at the time.

And when I look at review of the literature, I look at it personally and make a decision one way or the other. Whereas, in this case this group of people who were all supervised by me as part of my group did the literature search. But then this document after it was drafted was reviewed by the advisory committee. And they had some comments and suggestions on revisions. So that would be different than what I do specifically.

Q. I want to be a little bit more narrow in my question. In terms of deciding what literature to review and then what literature to reference in connection with the 1999 guideline, was that methodology any different than what you personally used in searching for, reviewing, and deciding what literature to reference in your opinion?

A. I'd say generally they would be the same. But if you get the specifics -- you know, this is obviously a very broad guideline. It tries to cover all components of surgical site infection prevention. It in fact is so broad that the recent CDC guideline revision did not undertake to do this broad a view but, rather, focused on -- I think it's either three or four specific surgical procedures. So we went very broad.

And I think one difference between what was done here and what I did is I tried to go very deep on a very narrow area: Normothermia, hypothermia, and the risk of infection. And basically methodologies to maintain normothermia and their impact.

So I'm going systematically very deep on a relatively narrow aspect. Whereas, this is trying to be comprehensive. But obviously if you're looking at such a broad range of different components, you may not go quite as deep.

Q. Again, my question may have been too broad and I -- see if I can clarify it.

A few moments ago you said that -- and the record is what it is; I'm not trying to put words in your mouth -- but that the CDC now will only look at

A. 19. Well, I probably started at least two years before that. But, yeah, over 15 years.
Q. Okay. And going back to the sentence where -- in your report where you say, "Exogenous sources account for the majority of SSIs," you didn't actually cite any medical literature for that proposition, did you?
A. No.
Q. You just said -- that was based on your years of experience at the CDC; right?
A. That was based on the outbreaks that we investigated when I was at CDC, as well as scientific literature.
Q. Could you turn on Exhibit 5 to page 103. Direct your attention to the first full paragraph on that page. Could you read that first full sentence.
A. The first full sentence?
Q. Beginning with, "For most SSIs."
A. "For most SSIs, a source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera."
Q. And for that there's a citation; correct?
A. Correct. A study from 1968.
Q. The Altameier, Culbertson, and Hummel study?

A. No. Actually --
Q. Did I get that wrong?
A. Oh. 57. Yes, yes. Right. 1968, right.
Q. So the sentence in your 1999 CDC guideline says, "Most pathogens are endogenous." And in your report you say "most are exogenous." Right?
A. Right. And the --
Q. Did something happen in the last four years of your CDC tenure to make you change your mind about everything you learned in the first 19?
MR. B. GORDON: Objection to form. Mischaracterizes the evidence. And argumentative.
THE WITNESS: Well, couple of things. One is it talks about endogenous. And then it talks also about exogenous organisms as a source of SSI include surgical personnel; operating room environment; all tools, instruments, materials brought to the sterile field during the operation. So it doesn't exclude those.
But if you look at what happened between this guideline -- and, actually, it started a little bit before this guideline -- but a tremendous number of interventions have been applied to patients to reduce the endogenous flora and the importance of the endogenous flora. Most of the Center for

Medicare/Medicaid services or CMS -- what's called SCIP measures -- which is a surgical care improvement -- surgical infection prevention.
Activities were really focused at the endogenous rather than exogenous flora. So, for instance, improvement of prophylactic antibiotics, improvement in skin antisepsis by the use of chlorhexidine alcohol rather than povidone iodine.
(Reporter asks for repetition.)
"Chlorhexidine alcohol rather than povidone iodine."
Those activities were really aimed at the endogenous flora. So there's really a lot of activities on endogenous flora; not as many necessarily on the exogenous flora.
BY MR. C. GORDON:
Q. Okay. So as of 1999 you were satisfied that the state of the medical literature was such that you could say that the majority of SSIs were caused by endogenous flora; right?
A. Right. As endemic infections, yes.
Q. And that's changed in the last 18 years for the reasons you mentioned; right?
A. Correct.
Q. Are you aware of any medical journal,

textbook, anything in the last 18 years that has said what you say, which is that the majority of SSIs are caused by exogenous sources?
A. Well, certainly the Seminars journal that we gave you a copy of that gives a list of all the outbreaks that CDC did as well as the role of the environment. There's a number of papers in that that document the role of exogenous sources of infection.
Q. My question is very specific. You were satisfied in 1999 that the majority were caused by endogenous sources. And you actually cited one published paper for that. In the 18 years since the 1999 guidelines were published, has any medical journal or textbook published any kind of a conclusion -- study, metanalysis, anything -- that concludes that now things have shifted so such that the majority of SSIs are exogenous?
MR. B. GORDON: Object to form; asked and answered.
THE WITNESS: Well, I don't know that I've done a search for, you know, every -- it wouldn't -- Medline search wouldn't pick up books anyway. But I'm not sure I've seen a specific paper looking at that.

As I say, the Seminars journal that we gave you shows all the CDC outbreaks that we investigated and the surgical site outbreaks in particular. Of the 22, 20 of the 22 -- actually, 21 of the 22 are exogenous sources of infection. The reference that we gave here is 1968. So it probably was changing even at this time.

BY MR. C. GORDON:

Q. Is the CDC called in for -- every time there's a surgical site infection?

A. I doubt it. They'd be kind of busy if they were. No.

Q. In fact, the CDC is not called in for the overwhelming majority of surgical site infections that occur every day and throughout the country; right?

A. Absolutely. Or healthcare-associated infections in general. And they have to be very specific in what they investigate. And we try to pick outbreaks that would advance the field of infection control and not be redundant of something that's been shown 20 times.

Q. Okay. So if patients are experiencing common surgical site infections that arise from endogenous flora that have been studied many times

over the years, that would probably not be something that would result in a CDC outbreak investigation?

MR. B. GORDON: Object to form.

BY MR. C. GORDON:

Q. Right?

MR. B. GORDON: Lack of foundation. Calls for speculation.

THE WITNESS: Well and that's probably not true. It depends on the organism. For instance, like the heater-cooler investigation was a very unusual organism. Very similar to what we're dealing with here with Bair Hugger where it was a device that was used for decades and thought to be perfectly safe. That then only was recognized as being a cause of infection because Mycobacterium chimaera infections were occurring in cardiac surgery patients. And that was very unusual. So certainly if the heater coolers have been associated with Staph aureus infections it probably would have taken a lot longer before it would have been recognized.

BY MR. C. GORDON:

Q. And my question went to garden variety infections. Let's take Staph epidermidis. That's a pretty common surgical site infection; isn't it?

A. Correct.

Q. And probably everybody in this room has Staph epidermitis bacteria; right?

A. Correct.

Q. Some maybe more than others.

A. Possibly.

MR. ASSAAD: For the record Corey Gordon just looked directly right at Mr. Assaad, which is myself, talking about Staph epidermis.

MR. C. GORDON: Are you feeling guilty? Sorry.

MR. ASSAAD: A little bit. I didn't take a shower this morning, so it might be less than most.

BY MR. C. GORDON:

Q. So a hospital experience as a single surgical site infection involving Staph epidermitis, that wouldn't be the type of thing that would result in CDC getting a call and starting an outbreak investigation; right?

MR. B. GORDON: Object to the form. Calls for speculation, the source of the outbreak.

THE WITNESS: Well, if it was the infecting pathogen, I think it's probably unlikely that it would lead to a CDC investigation. On the

other hand, if it were Staph epidermitis that had a very unusual antibiogram, for instance, so --

(Reporter asks for repetition.)

Antibiogram. So, for instance, when the first reported Staph aureus or MRSA that had vancomycin intermediate resistance --

(Reporter asks for repetition.)

Vancomycin intermediate resistance occur it was N of 1. And we investigated to try to identify what was going on.

Now, if it had been an MRSA or a Staph aureus with a very common antibiotic susceptibility pattern, we wouldn't have investigated probably.

BY MR. C. GORDON:

Q. And take away from that what the CDC investigates is unusual circumstances. A cluster of more infections than you would normally expect for an unusual type of pathogen.

MR. B. GORDON: No question yet.

BY MR. C. GORDON:

Q. Right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, it's a combination of factors. So it's unusual -- or I mean, it's an unusual antibiogram association with a medical

device that's not been known to be a source before like the heater-cooler. So there's a list of different possibilities of what would be investigated. But certainly every infection that occurs would not be investigated.

BY MR. C. GORDON:

Q. So the fact that 20 of the 21 investigations that you referred to that the CDC investigator proved to be exogenous sources, are you saying that that tells you that all the infections that you didn't investigate must also be predominantly exogenous?

MR. B. GORDON: Objection to form. Misstates his testimony.

THE WITNESS: Yeah, I wouldn't say it necessarily is -- is -- reflects that. But it does show that even though many of those were Staph aureus infections and some like Dr. Wenzel would say that's exogenous organisms. In fact, when we investigated them, they weren't. And without investigating them, you don't know.

BY MR. C. GORDON:

Q. I go back to my earlier question. Can you point me to any published medical literature in the last 18 years that says that now the majority of

SSIs are caused by exogenous sources?

MR. B. GORDON: Objection; asked and answered.

THE WITNESS: As I mentioned, that Seminars in Infection Control has a number of papers in there that would address that. I'm sure there are others in the published literature talking about the relative relationship between endogenous and exogenous sources.

BY MR. C. GORDON:

Q. When you say you're sure there are, have you done research to see if that's the case?

A. I have not looked recently. It would be pretty easy to do.

Q. But you didn't do that?

A. No.

Q. So when you said on page 5 of your report, "Exogenous sources account for the majority of SSIs," that was based on your own personal analysis; right?

A. Well, personal analysis as well as experience at CDC investigating outbreaks for 17 years.

Q. Well, you had had that experience in 1999 when you wrote, "For most SSIs, the source of

pathogens is the endogenous flora of the patient's skin"; right?

A. Well, I hadn't had it all in 1999. I had been there -- what? -- 19 -- 17 years probably when I started. It had been 19 years.

Q. Okay. And so --

A. So it was changing. And that is a reference from 1968, which is a few years before that.

Q. Well, in 1999 when you were applying the CDC gold standard methodology, I assume you took note of the fact that some study you were citing was 1968 and you would have done at least some research to see if that was still a valid study or if there were more contemporary things that called that into question; right?

A. I'm sure there was some literature reviewed, yes.

Q. And if you had found something post 1968, which challenged the statement that you put out in these guidelines, you would have at least considered it and perhaps mentioned it; right?

A. Well, we do mention in the next paragraph. It basically is a paragraph on endogenous and a paragraph on exogenous.

Q. Okay. I'm talking -- and again I understand there -- you talk about exogenous and endogenous.

You would agree with me that what you say in 1999 says that "more than 50 percent of SSIs are caused by endogenous sources." What you're saying now in this expert report is that more than 50 percent of SSIs are caused by exogenous sources; right?

MR. B. GORDON: Objection to form. And you're misquoting the citation you're referring to now, Corey. You're using "causes" instead of "sources." And before you were saying "sources." So just be clear for the record exactly what you're asking him.

BY MR. C. GORDON:

Q. And I'll accept that as a friendly amendment. My question relates to "sources," not "causes."

A. Okay. I think what we were trying to do in the SSI guideline is basically point out that both endogenous and exogenous sources of pathogens are important in patients undergoing SSIs.

The other thing is that this guideline is a guideline for all SSIs, not specific to prosthetic

MR. B. GORDON: Objection to the form. Also mischaracterization.

THE WITNESS: Well, there are certainly many endogenous and exogenous source possibilities. Some of which are -- or many of which you hopefully can eliminate.

BY MR. C. GORDON:

Q. And the only way you can eliminate them is if you investigate them; right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, you can do -- it depends on if it's a cluster or an individual case. Obviously if it's a cluster, trying to do an epidemiologic study can assist you in identifying whether it's personnel that are the source or potentially the patient or equipment.

BY MR. C. GORDON:

Q. And how do you do that in an individual case?

A. It's a little bit more difficult, but you look -- I think in the individual case, you also focus on kind of the timeline of events of what has happened and looking at all the different prevention interventions, some of which we've talked about such as skin prep, timing of prophylactic antibiotics,

breaks in aseptic technique, the duration of the procedure. So a lot of individual factors that may either increase or decrease the risk for infection occurring.

MR. B. GORDON: For the record I want to interpose an objection here.

I'll give you some latitude, Corey, but we're to talk about general causation today. There is a thing contemplated the other day for case-specific causation. Will be a different report, different deposition. But if you want to ask those questions today, then we're going to take the position that you're done after today.

BY MR. C. GORDON:

Q. Going back to -- I want to look back on page 127 where you talk about other well-established modes of transmission such as transient hand carriage by healthcare workers. How could you -- how -- what was your -- what -- strike that.

You -- you do say here that in outbreaks those were not investigated or eliminated. Would there have been a methodology for investigating or eliminating those?

A. Well, you could follow the same pattern of, you know, medical record review, and line

listing, epidemiologic studies to try to identify what the risk factors for infection are. And there certainly would be some ways to try to address that. It's obviously -- if the outbreak is ongoing, and it's probably easier to do than if the outbreak stopped two weeks ago. So it's a little -- the type of the investigation tends to be tailored to the specific outbreak and the timing of that outbreak and what's available, what's not as to what you can do.

Q. How do you define an outbreak?

A. Well, I think the generally accepted definition is it's the frequency of occurrence of an event that is above the baseline rate and reaches a statistical significance. And that's usually the definition that is used. And there is somewhat a differentiation of "epidemic" or "outbreak" from "endemic." So a lot of the infections that occur are endemic infections, particularly if it's a patient's own endogenous flora.

And so if you look at a hospital within, say, MRSA infection rate, they've got a long period of time where they've had MRSA infections and there's some kind of background rate of what that is. With an outbreak, it assumes that you have that

background rate or can calculate that background rate and then look at what the rate of event is during a putative outbreak period and then do a statistical analysis to see if the rate is increased statistically.

Q. One of the papers that you rely on for your opinion is the McGovern 2011 study. We talked a little bit about it earlier. It had bubble component to it. And it also had a -- an observational study component to it; correct --

MR. B. GORDON: Object to the form --

BY MR. C. GORDON:

Q. -- do you agree?

MR. B. GORDON: -- counsel's use of the word "reliance" -- "reliance" or "relied on," something like that.

What's the question?

BY MR. C. GORDON:

Q. Well --

A. The question was whether they had two components or not?

Q. Do you rely on the McGovern study?

MR. B. GORDON: Objection to counsel's characterization, use of the word "rely."

THE WITNESS: As I said before, I look at

all of the papers that I've read, my experience; you know, 23 years at CDC, both in terms of outbreak investigations, developing surveillance definitions, assisting with the development of the surveillance system and knowing surveillance data. All of that is incorporated in how I look at the data and how I reach the conclusions in my report. So certainly the Albrecht study was one of many that I looked at that --

BY MR. C. GORDON:

Q. You mean the McGovern -- well, Albrecht was an author. You're talking about McGovern?

A. McGovern was one of many that I referenced in my report.

Q. Was there any other study that you referenced in your report that purported to show a relative risk of Bair Hugger versus some other warming modality in terms of joint infections?

A. No. That was -- that was the solid one.

Q. So you -- before -- I assume before you decided whether that was something worthy of your inclusion in your report, you wanted to -- see if I can find your exact phrase -- you wanted to look critically and evaluate all the data, not just some of the data; right?

A. Correct.

Q. So did you do that with the McGovern paper?

A. Yes.

Q. Okay. Well, did you -- in considering the McGovern paper, did you look at the specific pattern of infections?

A. I'm not sure what you mean by "pattern."

Q. Well, the -- okay. Did you -- when you were looking critically in evaluating all the data, did you look at the individual infection types that were occurring during the study, the two arms of the study period?

A. When you mean infection types, you mean the pathogens?

Q. The pathogens, the bugs.

A. I certainly looked at that, yeah.

Q. And how did -- well, what -- what did you look at to -- to assess that?

A. You mean specifically what did I look at?

Q. Right. Are you talking about just what was printed in the study, or did you look at anything else?

A. I looked at a line list that I believe was one of the exhibits.

MR. C. GORDON: See if this helps.

(Exhibit 18 marked.)

BY MR. C. GORDON:

Q. I'll show you what's been marked as Exhibit Jarvis 18. Previously marked as McGovern Exhibit 16.

A. Yeah, that looks like it.

Q. So you reviewed this in your -- looking critically in evaluating all the data of the McGovern study; is that right?

A. Right.

Q. Did you -- let's focus on Staph aureus, both methicillin susceptible and methicillin resistant.

Did you look at the number of Staph aureus cases that occurred during the Bair Hugger-only period and compare that to the number of Staph aureus cases that occurred during the HotDog-only period?

A. Yes.

Q. And what did you find?

A. First of all, I found that my eyes are not good and I needed a --

Q. Copy that.

A. -- magnifier for this thing. That was the

first thing I learned.

Second I learned that it's hard to read and there's duplication of information in it. And I believe that -- I'm trying to see the -- I had them lined up so it made it easier to see. But I guess over here is -- that during the HotDog period, there were infections caused by Staph epidermidis, Enterococcus but none by Staph aureus.

Q. And during the HotDog -- strike that.

So during the HotDog period there was zero Staph aureus infections; correct?

A. There were only three infections but, yeah, none were Staph aureus.

Q. And you read Dr. Reed's testimony where he said there should have been an additional infection in the HotDog --

A. Right.

Q. -- arm, correct?

A. Right. I don't know what the pathogen was with that one. It might have been Staph aureus; I don't know.

Q. And in the Bair Hugger-only period, how many Staph aureus infections were there?

A. I don't know that I counted them.

MR. B. GORDON: Just for the record while